ENDOSKOPE FÜR MEDIZIN UND TECHNIK
INSTRUMENTE FÜR OTO-RHINO-LARYNGOLOGIE

KARL STORZ SE & Co. KG • Postfach 230 • 78503 Tuttlingen/Germany

Ihre Zeichen	Ihre Nachricht vom	Unsere Zeichen	Datum
			18.12.2019 г.

Corrective action – high-frequency generators Autocon III 300 and Autocon III 400

Ladies and gentlemen,

Due to regulatory requirements, we would like to inform you about the following **corrective action** in connection with our high-frequency generators Autocon III 300 and Autocon III 400. This is not a product recall but an update of the device software.

We would like to point out at the outset that the Autocon III 300 and Autocon III 400 devices have not posed a risk to patients, users, or third parties in the past and do not currently do so either.

Your KARL STORZ representative will contact you by January 31, 2020 to arrange an appointment with you on site for the installation of the software update.

Furthermore, we ask you to complete and return the enclosed feedback form to us by January 13, 2019 at the latest.

We would like to thank you very much for your understanding for this corrective action and apologize for any inconvenience.

Very truly yours,

KARL STORZ SE & Co. KG

p.p. Robert Herz
- Department Manager Vigilance -

Urgent Field Safety Notice

Update of device software for Autocon III 300

and Autocon III 400

(2019-12-18)

Sender:
KARL STORZ SE & Co. KG
Dr. Karl-Storz-Str. 34
D-78532 Tuttlingen, Germany

Addressee:
All users and operators

Affected products:

UH300	(Autocon III 300)
UH300U	(Autocon III 300 110 V-Variant)
UH400	(Autocon III 400)
UH400U	(Autocon III 400 110 V-Variant)
UH401	(Autocon III 400 BIVASCULARSAFE)
UH401U	(Autocon III 400 BIVASCULARSAFE 110 V-Variant)

A. Description of the problem including the identified cause:

Indication-related designation of functionalities

In some cases, the functional modalities (modes) to be selected were designated with indication-related terms. We have recognized that it can be misleading for the user or operator if technical functionalities have an indication-related designation, as no treatment recommendation should be made. The Autocon III 300 and Autocon III 400 are devices that are not in contact with patients and that provide high-frequency energy. The function modes to be selected refer exclusively to technical properties. In accordance with the clinical evaluation, the functionalities (modes) to be selected may only have technical designations in the future.

B. Description of the corrective action:

In the course of the conformity assessment, we have checked our technical data and adapted it to the latest regulations. This now results in the following corrective action:

Renaming of functionalities

In order to implement the most current regulations and to solve the problem described above, we have developed a software update so that in the future, the functionalities (modes) of the Autocon III 300 and Autocon III 400 to be selected will have only technical and not indication-related designations.

This means that – with a few exceptions – all technical functionalities will continue to be available to you as the user or operator of the medical device, although under a purely technical name.

The modes that will be available in the future can be found in the enclosed excerpt of the user manual. We will install these new designations on your device via a software update.

Once the software has been updated, the medical user will select the technical mode with the technical properties that are appropriate for the application in question. In addition, the software will provide the possibility for each user to rename the available modes with terms of his or her choice. For traceability reasons, Autocon will receive a new material number and a corresponding new nameplate (UH400**E**/ UH400U**E**/ UH401**E**/ UH401U**E** and UH300**E**/ UH300U**E**) after its update. The serial number will not change.

C. Risk for patients, users, or third parties when continuing to use the product:
As this device does not pose a risk to patients, users, or third parties, the product can continue to be used until the software update is installed.

D. Risks for patients who have already been treated with affected products:
No further measures are necessary for patients who have already been treated.

E. Timetable for the action:
Your KARL STORZ representative will contact you by January 31, 2020 to arrange an appointment with you on site for the installation of the software update.

F. What measures are to be taken by the addressee?
Please confirm the receipt of this letter with the enclosed feedback form.

G. Contact for technical questions:
If you have any technical questions, please contact your local KARL STORZ representative.

H. Contact for regulatory questions:
KARL STORZ SE & Co. KG
Robert Herz
Tel.: +49 (0)7461 708 7348 (during business hours)
Fax: +49 (0)7461 708 45581

I. Transmission of the urgent field safety notice:

This **urgent field safety notice** must be passed on to all users of the products listed above and all other persons who need to be aware within your organization. If you have transferred these products to third persons, please transmit a copy of this notice or alert the contact listed below. Please keep this notice at least until the corrective action has been fully implemented.

The German Federal Institute for Drugs and Medical Devices has received a copy of this urgent field safety notice.

We thank you for your cooperation and understanding for this measure.

Very truly yours,

KARL STORZ SE & Co. KG

p.p. Robert Herz
- Department Manager Vigilance -

Feedback form

This is not a product recall – please do not return any products!

We hereby confirm that the safety information has been received and, where applicable, passed on.

Please send this form to:
vigilance@karlstorz.com

or

Fax: +49 (0)7461 708 45581

or by post to

KARL STORZ SE & Co. KG
Attn: Robert Herz
- Department Manager Vigilance -
Dr. Karl-Storz-Str. 34
78532 Tuttlingen, Germany

Hospital or organization (stamp):

I confirm that I have read and understood the safety instruction and that I have implemented it accordingly.

Name: _____

Title/position: _____

Signature: _____

Date: _____